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510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: September 13, 2004

1. Contact Person

Bridget Gardner
Manager, Regulatory Affairs
(508) 261-6384

2. Name of Medical Device

Classification Name:	Tubes, Gastrointestinal (and accessories)
Common or Usual Name:	Gastrointestinal tube accessory
Trade Name:	Kendall CO_2nfirm NOW™ CO_2 Detector

3. Legally Marketed Devices to Which Substantial Equivalence Is Claimed
   - Easy Cap® CO_2 detector, 510(k) number K894053, cleared on 7/20/89
   - Pedi-Cap® CO_2 detector, 510(k) number K944400, cleared on 9/27/94

4. Device Description
The Kendall CO_2nfirm NOW™ CO_2 Detector is a disposable device that is used during the oral or nasal placement of a gastric tube to preliminarily determine if the tube is properly placed by detection of CO_2.

5. Device Intended Use
Used to assist verification of tube location during oral or nasal placement of a gastric tube in adults.

6. Product Comparison
The proposed device has the same technological characteristics as the predicate devices. Both the proposed and predicate devices function by colorimetric detection of CO_2 in air. The construction and materials of the devices, as well as the detector chemistry and sensitivity are identical between the proposed and predicate devices. The inlet and outlet ports of the proposed device have been modified to accommodate the new intended use, and the device printing has been modified to replace the quantitative scale with a qualitative (yes/no) scale.

510(k) Summary (Continued)

7. Nonclinical Testing

Testing was conducted to demonstrate that the design of the proposed device was equivalent to the predicate devices, and/or met the industry accepted criteria for such devices as defined in EN1615:2000 and ISO 594, Parts 1&2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Ms. Bridget Gardner
Manager, Regulatory Affairs
Kendall
TYCO Healthcare Group, LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K042572
Trade/Device Name: Kendall CO_2nfirm NOW™ CO_2 Detector
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: September 13, 2004
Received: September 21, 2004

Dear Ms. Gardner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K042572

Device Name: **Kendall CO_2nfirm NOW™ CO_2 Detector**

Indications For Use:

Used to assist verification of tube location during oral or nasal placement of a gastric tube in adults.

Prescription Use _V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042572